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09/786,072	03/14/2001	Thomas Koehler	WEH204	6854

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Horst M Kasper
13 Forest Drive
Warren, NJ 07059

EXAMINER
STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
1637	16

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,072	KOEHLER, THOMAS	
	Examiner	Art Unit	
	Teresa E Strzelecka	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2002 and 22 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☒ Claim(s) *1-29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. This Office action is in response to amendments filed on August 8, 2002 and January 22, 2003.

2. In the amendment of August 8, 2002, Applicant amended claims 1-16 and added new claim 17-29. Claims 1-29 are pending and will be examined.

3. Applicant's amendments of claims 1-16 introduced new grounds for rejection under 35 U.S.C. 112, second paragraph. Rejection of claims 1-5 under 35 U.S.C. 102(b) over Day et al. is maintained (see *Response to Arguments* below).

Response to Arguments

4. In response to applicant's argument that the Day et al. reference teaches dried template DNA and dried PCR nucleotides, but no standard DNA, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Standard DNA is any piece of DNA that can be used as a standard in a particular reaction, for example, PCR. Therefore the fact that the dried DNA is intended for use as a standard does not distinguish it from any other dried DNA.

Claim Objections

5. Claim 1 is objected to because of the following informalities:

a) no comma between "calibrated nucleic acids" and "said standard nucleic acids",

b) the phrase "which neither requires chemical nor biochemical modification prior to coating" would be made clearer by changing it to "which require neither chemical nor biochemical modification prior to coating", since this part seems to refer to the reaction chambers,

c) there is a quotation mark at the end of claim 1.

6. Claim 6 is objected to because of the phrase "adsorbed directly in the inner wall". A more grammatically correct, and clearer, phrase would be "adsorbed directly onto the inner wall".

7. Claim 14 is objected to because of the phrase "oligonucleotides acting as primers". The method of claim 6 does not include amplification steps, so the primers are not taking part in any active process. A more appropriate phrase would be simply "oligonucleotide primers". In addition, the claim would be clearer if presented in a Markush group format.

8. Claim 17 is objected to because of the phrase "adsorbing directly ... in the inner wall". A more grammatically correct, and clearer, phrase would be "adsorbing directly ... onto the inner wall".

9. Claim 25 is objected to because of the phrase "oligonucleotides acting as primers". The method of claim 17 does not include amplification steps, so the primers are not taking part in any active process. A more appropriate phrase would be simply "oligonucleotide primers". In addition, the claim would be clearer if presented in a Markush group format.

10. Claim 28 is objected because of the word "vesselsl".

11. Claim 29 is objected to because of the phrase "adsorbing directly ... in the inner wall". A more grammatically correct, and clearer, phrase would be "adsorbing directly ... onto the inner wall".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 1 is indefinite over the recitation of "said standard nucleic acids". There is insufficient antecedent basis for this limitation in the claim. There is no mention of standard nucleic acids anywhere else in claim 1.

B) Claim 3 recites the limitation "said DNA, RNA synthetic equivalents of DNA and/or RNA, as well as dU-containing DNA" in lines 1, 2. There is insufficient antecedent basis for this limitation in the claim. Claim 3 depends from claim 1, and there is no mention of any of these types of nucleic acids in claim 1.

C) Claim 4 is indefinite over the recitation of "wherein said". It is not clear to what part of claim 1 does "said" refer to.

D) Claim 4 is indefinite over the recitation of "a DNA solution is used comprising a minimum sequence homology to the nucleic acid compound". It is not clear how a solution can have sequence homology to a nucleic acid.

E) Claim 5 is indefinite over the recitation of "said carrier nucleic acid". There is insufficient antecedent basis for this limitation in the claim. There is no mention of carrier nucleic acid in claim 1, there is a limitation "carrier nucleic acids".

F) Claim 6 is indefinite because it does not recite positive method steps. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active

fashion. See Ex parte Erlich, 3 USPQ2d, p. 1011 (Bd. Pat. App. Int. 1986). It is suggested that the claims be rewritten such that they set forth defined methods, such as by reciting "[a] method of..., comprising the steps of ...", after which a series of active steps is recited, for example "obtaining a biological sample" or "hybridizing a probe to said biological sample, wherein said probe...".

G) Claim 6 is indefinite over the recitation of "said calibrated standard nucleic acids". There is insufficient antecedent basis for this limitation in the claim. There is no mention of calibrated standard nucleic acids anywhere else in claim 6.

H) Claim 8 recites the limitation "said DNA, RNA synthetic equivalents of DNA and/or RNA, as well as dU-containing DNA" in lines 1, 2. There is insufficient antecedent basis for this limitation in the claim. Claim 8 depends from claim 6, and there is no mention of any of these types of nucleic acids in claim 6.

I) Claim 9 is indefinite over the recitation of "wherein said". It is not clear to what part of claim 6 does "said" refer to.

I) Claim 9 is indefinite over the recitation of "a DNA solution is used comprising a minimum sequence homology to the nucleic acid compound". It is not clear how a solution can have sequence homology to a nucleic acid.

E) Claim 10 is indefinite over the recitation of "said carrier nucleic acid". There is insufficient antecedent basis for this limitation in the claim. There is no mention of carrier nucleic acid in claim 1, there is a limitation "carrier nucleic acids".

F) Claim 11 is indefinite over the recitation of "said coating". There is insufficient antecedent basis for this limitation in the claim. There is no limitation of "coating" in claim 6, from which claim 11 depends.

G) Claim 11 is indefinite over the recitation of "the arbitrarily chosen concentration". There is insufficient antecedent basis for this limitation in the claim. There is no limitation of "arbitrarily chosen concentration" in claim 6, from which claim 11 depends.

H) Claim 11 is indefinite over the recitation of "the analyte nucleic acid". There is insufficient antecedent basis for this limitation in the claim. There is no limitation of "analyte nucleic acid" in claim 6, from which claim 11 depends.

I) Claim 16 is indefinite because it is not clear what is the relationship between the test kits, two oligonucleotides and carrier nucleic acid. Are the two oligonucleotides and the carrier nucleic acid part of the test kit or are they being used separately?

J) Claim 18 is indefinite because it is not clear whether "further comprising coating plastic vessels or glass capillaries" means that other reaction chambers are prepared, in addition to the reaction chambers of claim 17.

K) Claim 19 is indefinite because it is not clear whether "further comprising employing DNA, RNA..." means that these nucleic acids are added in addition to the standard and carrier nucleic acids already in the chamber. Since "employing" is understood to mean "using", it is also not clear what these different nucleic acids are being used for.

L) Claim 20 is indefinite over the recitation of "further comprising employing a DNA solution..., and employing a tRNA solution". It is not clear how these solutions are being used in the method.

M) Claim 20 is indefinite over the recitation of "a DNA solution is used comprising a minimum sequence homology to the nucleic acid compound". It is not clear how a solution can have sequence homology to a nucleic acid.

N) Claim 21 is indefinite over the recitation of "further comprising employing a DNA of a lambda phage..". It is not clear how this DNA is being used in the method.

O) Claim 23 is indefinite over the recitation of "the arbitrarily chosen concentration". There is insufficient antecedent basis for this limitation in the claim. There is no limitation of "arbitrarily chosen concentration" in claim 17, from which claim 23 depends.

P) Claim 23 is indefinite over the recitation of "the analyte nucleic acid". There is insufficient antecedent basis for this limitation in the claim. There is no limitation of "analyte nucleic acid" in claim 17, from which claim 23 depends.

R) Claim 25 is indefinite over the recitation of "further comprising employing at least two oligonucleotides acting as primers". It is not clear how these oligonucleotides are being used in the method.

S) Claim 27 is indefinite because it is not clear what is the relationship between the test kits, two oligonucleotides and carrier nucleic acid. Are the two oligonucleotides and the carrier nucleic acid part of the test kit or are they being used separately?

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. The following rejection is based on the product claimed in claim 1, which is "Reaction chambers coated with native, synthetically or enzymatically prepared nucleic acids", irrespective of the way in which they were obtianed (see MPEP 2113).

MPEP 2113 Product-by-Process Claims

PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

16. Claims 1-5 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Day et al. (Biotechniques, vol. 18, pp. 981-984, 1995).

Day et al. teach 96-well plates coated with DNA templates which were dried in the wells. The plates can then be used for setting up PCR reactions. Alternatively, PCR primers are distributed into the wells and dried there. In both cases, adherence of the dried DNA to the walls of the wells is non-covalent, since both dried template and dried primers function in subsequent PCR reactions (page 381-383).

17. No references were found teaching or suggesting claims 6-28, but they are rejected for reasons given above.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
April 22, 2003

TS

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

4/23/03